

COMPLAINT ANALYSIS

1.0 INTRODUCTION

The information reported herein provides an analysis of reported complaints received for a period of 18 years for the Smooth Low Bleed Gel-Filled Mammary Prostheses and the Textured Low Bleed Gel-Filled Mammary Prostheses. These data presented in this analysis are based on events reported from the complainants.

2.0 DATA COLLECTION

Complaints are reported to Mentor in accordance with 21 CFR 820 §198 and maintained in Mentor's InfoMed system, Version 7.0b for Windows 95 and NT (MakroMed Inc.). The system is designed to capture all reports of customer complaints and is administered by the Product Evaluation Group. The reported complaints are related to the identity, quality, durability, reliability, safety, effectiveness, or performance of Mentor products. This process was detailed in the Manufacturing Section, Module 2, Volume 2 of this PMA (M020018).

3.0 DATA ANALYSIS

The devices included in this complaint analysis are the Smooth Low Bleed Gel-Filled Mammary Prosthesis and the Textured Low Bleed Gel-Filled Mammary Prosthesis. These include the Round Low Profile, Round Moderate Profile, Round Moderate Plus Profile, Round High Profile, and Oval shapes for the smooth devices. For the textured devices, specific shapes included in this analysis are the Round Moderate Profile, Round Moderate Plus Profile and Round High Profile.

In estimating complaint rates, product complaint data from the InfoMed system provided the numerators, and sales data provided the denominators. The product complaint data included domestic complaints from 1985 to September 30, 2003. The sales data consisted of sales figures for the same period and only included domestic shipments of devices manufactured in Goleta, California or Irving, Texas and distributed in the United States.

Of the 8060 complaints reviewed in this report, 1714 (21.2%) of these devices demonstrated no abnormality upon completion of analysis by Mentor's Product Evaluation department (674 smooth devices (8.36%) and 1040 textured devices (12.9%)). In addition, 3841 (47.6%) of these devices were never returned to Mentor for analysis (1608 smooth devices (19.9%) and 2233 textured devices (27.7%)). As such, although the device was unavailable for analysis, the complaint was factored into the analysis as reported by the complainant.

Several of the complaint codes were grouped in this analysis as they report the same basic information. Specifically, complaints pertaining to Packaging and Labeling, Cosmetic and Particulate Matter, Rupture and Leakage, Exposure/Extrusion and

Necrosis, Hematoma and Seroma were combined. Complaints relating to products damaged during shipping were not reported in the post-implantation analysis but are included in a separate pre-implantation analysis. Additionally, all complaints categorized as "Intraoperative" and "After Surgery, Same Day" were grouped under Year 0 for time of occurrence or time *in vivo*.

The calculation of rates for Year 0 is based upon ½ the sales numbers for that year.

Complaint data were analyzed separately according to whether the complaint was pre- or post-implantation. Pre-implant complaints were categorized by year of complaint. Post-implantation complaints were analyzed by the year of complaint as well as years *in vivo*. Years *in vivo* was calculated by subtracting the year of sale of the implant from the year the problem was observed or reported. If the year the problem was observed was missing, then years *in vivo* was calculated by subtracting the year of implant from the year of explant. In cases where both the year the problem was observed and the year of explant (if any) were missing, years *in vivo* was considered missing and was categorized as unknown. Data were also analyzed overall, which includes reported events for all types of Low Bleed Gel-Filled Mammary Prostheses.

N/A refers to data that is "Not Available" and applies specifically to the textured gel devices. These devices were introduced three years after the smooth gel devices.

4.0 Results

4.1 Sales Data

Table 1 presents numbers of implants sold by type and year. Sales data for Smooth Low Bleed Gel-Filled Mammary implants are reported for 1985 through 2003; the cumulative total is 121,464. Textured Low Bleed Gel-Filled Mammary implants were sold beginning 1987 and are reported through September 30, 2003. Cumulative sales data for these implants is reported as 193,458. Reported cumulative sales for both the Smooth Low Bleed Gel-Filled Mammary Implants and the Textured Low Bleed Gel-Filled Mammary Implants are 314,922.

4.2 Complaint Data

4.2.1 Post-implantation complaints

Post-implantation complaints (as reported by the complainant) are presented in Tables 2 and 3 by the year the complaint was reported and by years *in vivo*, respectively. Numbers of complaints are presented overall and by implant type. Overall complaints included all gel-filled devices implanted from 1985 to 2003. Complaints are also presented by implant surface texture type.

Overall (for all types of Mentor gel-filled devices), the largest number of complaints were for rupture/leakage. A total of 3490 rupture/leakage complaints were received over the 18 years of implant experience. This represents 1.11% of all devices (314,922) sold for this time period. Other complaints which numbered more than 500 during the 18 year's experience were limited to capsular contracture (1292); 0.4%.

Table 4 presents post-implantation complaint rates per years *in vivo*, overall and by implant type. Overall, the rupture/leakage rate was 1.11%, capsular contracture was 0.41%, pain (non-breast related) was 0.15% and autoimmune type symptoms were 0.11%. All other reported complaints were less than 0.10%.

Rupture/leakage, capsular contracture, pain (non-breast related) and autoimmune type symptoms by type of implant were as follows: for smooth gel implants rupture/leakage was 1.46%, capsular contracture was 0.44%, pain (non-breast related) was 0.21% and autoimmune type symptoms were 0.16%; for textured gel implants, rupture/leakage was 0.89%, capsular contracture was 0.39%, pain (non-breast related) was 0.12% and autoimmune type symptoms was 0.07%.

Other complaint rates greater than 0.01% were as follows: smooth gel implants: breast pain 0.08%, bubbles 0.02%, cosmetic/particulate matter 0.02%, defective 0.05%, infection 0.05%, injuries 0.07%, joint pain 0.02%, no code available (device implanted) 0.08%, silicone (fear) 0.04%, and tear/hole 0.11%. For textured gel implants, complaint rates greater than 0.01% were as follows: asymmetry 0.02%, breast pain 0.11%, bubbles 0.10%, cosmetic/particulate matter 0.02%, defective 0.02%, exposure/necrosis 0.02%, hematoma/seroma 0.09%, infection 0.14%, injuries 0.03%, no code available (device implanted) 0.04%, tear/hole 0.10%, wrinkle 0.07%.

Figures 1 and 2 show rates by years *in vivo* by type of implant for rates higher than 0.25% (rupture/leakage, and capsular contracture). Notably none of these rates appear to increase over time.

4.2.2 Pre-implantation Complaints

Reports of complaints prior to implantation (out of box failures) are summarized in Table 5 overall and by implant type. The table shows the numbers of pre-implantation complaints for a cumulative total of 314,922 devices sold (121,464 smooth gel devices and 193,458 textured gel devices) for the period of 18 years. Overall, pre-implantation complaint rates were 0.11%. Pre-implantation complaint rates for the smooth gel devices were 0.059% and 0.14% for textured gel devices.

Most frequently reported pre-implantation complaints were bubbles and cosmetic related. Bubble rates were 0.02% for smooth gel devices and 0.100% for textured gel devices (0.070% overall). Cosmetic rates were 0.021% for smooth gel devices and 0.017% for textured gel devices (0.018% overall).

5.0 Conclusions

During the eighteen-year period from 1985 through 2003, Mentor Corporation sold 314,922 gel-filled breast implants of the following types: Smooth Low Bleed Gel-Filled devices and Textured Low Bleed Gel-Filled devices. Only the smooth gel devices were sold for the entire duration. Mentor began marketing the textured gel-filled devices in 1987.

During the this eighteen-year period a total of 8,060 post-implantation complaints and 345 pre-implantation or "out-of-box" complaints were received and investigated by Mentor. This represents a 2.56% post-implantation complaint rate and 0.11% pre-implantation rate for all devices. Most frequently reported post-implantation complaints were rupture/leakage, reported at a rate of 1.11%, capsular contracture at a rate of 0.41% pain (non-breast related) at a rate of 0.15% and autoimmune type symptoms were 0.11%.

Figures 1 and 2 show rates by years *in vivo* by type of implant for rates higher than 0.25% (rupture/leakage, and capsular contracture). These trends decrease over time.

It is interesting to note that the number of post-implantation complaints significantly increased starting in 1992. This increase in complaints may be due to factors including the public's heightened awareness of silicone breast implants.

The trends for the most frequently reported complaints for Mentor Low Bleed, Gel-Filled devices are found to be lower than the complication rates reported in the known published literature.

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Table 1

Number of Implants Sold by Type of Implant and Year

Year	Smooth Gels		Siltex Gels		Overall	
	Number Sold	Cumulative Total	Number Sold	Cumulative Total	Number Sold	Cumulative Total
1985	3864	3864	0	0	3864	3864
1986	10710	14574	0	0	10710	14574
1987	11695	26269	122	122	11817	26391
1988	10811	37080	4638	4760	15449	41840
1989	9172	46252	12771	17531	21943	63783
1990	6949	53201	16497	34028	23446	87229
1991	3010	56211	14794	48822	17804	105033
1992	-3016	53195	0	48822	-3016	102017
1993	1430	54625	11694	60516	13124	115141
1994	575	55200	9386	69902	9961	125102
1995	422	55622	8782	78684	9204	134306
1996	-46	55576	1970	80654	1924	136230
1997	-65	55511	10136	90790	10071	146301
1998	-27	55484	10357	101147	10330	156631
1999	-8	55476	14913	116060	14905	171536
2000	6953	62429	20080	136140	27033	198569
2001	9368	71797	18453	154593	27821	226390
2002	19123	90920	20185	174778	39308	265698
2003	30544	121464	18680	193458	49224	314922

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Table 2(a)
Number of Post-Implantation Complaints by Year of Complaint (Smooth and Textured Devices)

Complaint	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total
ADVERSE REACTIONS	0	0	0	0	0	2	0	7	6	6	0	0	0	0	0	0	0	0	0	21
ANXIETY, STRESS, DEPRESSION	0	0	0	0	0	0	0	3	6	9	0	0	0	0	0	0	0	1	0	19
ASYMMETRY	0	0	0	0	0	3	7	4	6	15	10	1	1	3	0	0	4	0	0	54
AUTO-IMMUNE TYPE SYMPTOMS	0	0	0	0	0	0	4	72	110	94	20	12	10	7	0	4	0	2	0	335
BREAST PAIN	0	0	0	0	0	0	5	40	45	119	73	20	3	8	3	4	1	1	2	324
BUBBLES	1	1	2	7	22	58	32	17	29	13	14	1	2	0	1	9	1	2	7	219
CAPSULAR CONTRACTURE	0	0	0	1	0	0	4	188	233	331	175	55	29	76	37	41	44	54	24	1292
COSMETIC/PARTICULATE MATTER	0	0	2	5	27	5	3	0	0	0	1	1	2	0	0	1	3	3	3	57
DEATH	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1
DEFECTIVE	0	0	0	13	73	0	0	4	0	0	0	0	0	0	0	0	0	0	1	92
DEFORMATION	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
DELAYED WOUND HEALING	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
DISLIKED RESULT	0	0	0	0	1	0	0	0	0	0	0	0	1	2	0	0	0	0	1	14
EXPOSURE/EXTRUSION/NECROSIS	0	0	0	0	1	0	0	0	0	0	2	0	0	0	2	0	0	2	1	8
FEVER	0	0	0	0	0	2	3	5	0	9	6	9	1	0	0	0	1	2	3	44
FLUID BUILD-UP	0	0	0	0	0	0	3	2	2	4	1	0	0	0	0	0	0	0	0	12
GEL BLEED	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2
HEMATOMA/SEROMA	0	0	0	0	0	2	8	1	52	22	51	33	1	1	4	2	0	2	0	181
HYPERTROPHIC SCARRING	0	0	0	0	0	0	0	4	11	12	9	0	0	2	0	0	0	0	0	38
DISPLACEMENT/MIGRATION	0	0	0	0	0	0	0	5	1	1	2	1	2	2	0	0	1	1	1	17
INFECTION	0	0	0	0	4	9	17	21	73	61	32	11	14	8	9	19	6	18	22	324
INFLAMMATION/IRRITATION/ SWELLING	0	0	0	0	0	1	1	6	8	8	14	0	0	3	1	0	0	2	0	44
INJURIES	0	0	0	0	0	0	0	5	117	10	0	0	0	0	0	0	0	0	0	132
JOINT PAIN	0	0	0	0	0	0	4	8	2	17	2	0	0	0	0	0	0	0	0	33
LOSS OF BREAST SENSATION	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2
LYMPHADENOPATHY	0	0	0	0	0	0	0	4	5	12	1	2	0	2	0	0	0	0	2	28
NO CODE AVAILABLE	1	4	10	3	3	4	6	31	36	43	10	0	1	3	1	1	7	8	4	176
OPEN CAPSULOTOMY	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
PACKAGING/LABELING	0	1	2	3	2	5	6	1	5	0	2	2	4	0	1	3	3	2	2	44
PAIN	0	0	0	0	0	1	20	80	139	180	17	8	5	8	7	1	5	4	4	479
RUPTURE/LEAKAGE	21	44	85	105	33	35	60	202	229	286	208	188	211	259	236	284	301	317	386	3490
SILICONE (FEAR)	0	0	0	0	0	2	6	33	29	4	3	0	0	0	0	0	0	0	0	77
SILICONE GRANULOMA	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	2	0	0	3
SLOSHING	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	2
STERILITY	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	4
TEAR/HOLE	0	0	0	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	0	4
WRINKLE	2	0	2	0	12	142	84	5	27	8	1	3	5	2	3	2	5	3	9	315
WRONG SIZE	0	1	0	0	3	2	5	11	15	26	11	4	14	14	3	12	16	8	8	153
More than 3 codes	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	17
Total	25	51	103	138	186	284	273	789	1173	1348	661	316	305	404	306	382	403	431	482	8060

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Table 2(b)
Number of Post-Implantation Complaints by Year of Complaint (Smooth Devices)

Complaint	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total
ADVERSE REACTION	0	0	0	0	0	0	0	1	2	6	0	0	0	0	0	0	0	0	0	9
ANXIETY, STRESS, DEPRESSION	0	0	0	0	0	0	0	2	0	8	0	0	0	0	0	0	0	0	0	10
ASYMMETRY	0	0	0	0	0	3	1	1	0	8	4	0	0	0	0	0	0	0	0	17
AUTO-IMMUNE TYPE SYMPTOMS	0	0	0	0	0	0	2	42	74	53	10	7	3	0	0	4	0	2	0	197
BREAST PAIN	0	0	0	0	0	0	0	22	21	39	13	2	1	1	0	1	1	0	2	103
BUBBLES	1	1	2	1	0	4	3	1	4	2	0	0	0	0	0	5	0	0	2	26
CAPSULAR CONTRACTURE	0	0	0	1	0	0	2	107	152	138	50	10	8	11	3	8	10	28	11	539
COSMETIC/PARTICULATE MATTER	0	0	2	3	7	4	1	0	0	0	0	0	0	0	0	0	2	3	3	25
DEFECTIVE	0	0	0	11	44	0	0	1	0	0	0	0	0	0	0	0	0	0	1	57
DELAYED WOUND HEALING	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	2
DISLIKED RESULT	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	3
EXPOSURE/EXTRUSION/NECROSIS	0	0	0	0	1	0	2	0	2	1	1	0	0	0	0	0	0	0	2	9
FEVER	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	3
HEMATOMA/SEROMA	0	0	0	0	0	0	0	0	2	3	5	0	0	0	1	0	0	0	0	11
HYPERTROPHIC SCARRING	0	0	0	0	0	0	0	4	5	2	1	0	0	0	0	0	0	0	0	12
DISPLACEMENT/MIGRATION	0	0	0	0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0	3
INFECTION	0	0	0	0	1	0	2	4	20	11	0	1	0	1	0	2	2	4	7	55
INFLAMMATION/IRRITATION/ SWELLING	0	0	0	0	0	0	0	6	6	2	1	0	0	0	0	0	0	2	0	17
INJURIES	0	0	0	0	0	0	0	3	66	10	0	0	0	0	0	0	0	0	0	79
JOINT PAIN	0	0	0	0	0	0	4	8	2	16	0	0	0	0	0	0	0	0	0	30
LOSS OF BREAST SENSATION	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
LYMPHADENOPATHY	0	0	0	0	0	0	0	2	2	4	0	0	0	0	0	0	0	0	0	8
NO CODE AVAILABLE	1	4	10	3	1	1	1	13	20	29	2	0	0	2	0	1	3	4	4	99
OPEN CAPSULOTOMY	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1
PACKAGING/LABELING	0	1	2	3	1	3	1	0	2	0	0	0	0	0	0	2	1	1	0	17
PAIN	0	0	0	0	0	0	9	45	79	105	4	4	3	0	3	0	0	0	0	252
RUPTURE/LEAKAGE	21	44	85	78	21	23	36	140	164	189	130	109	82	109	89	95	94	108	155	1772
SILICONE (FEAR)	0	0	0	0	0	0	0	4	21	19	2	3	0	0	0	0	0	0	0	49
SLOSHING	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	2
TEAR/HOLE	2	0	2	0	3	72	29	0	4	2	0	1	0	0	1	1	3	3	8	131
WRINKLE	0	1	0	0	0	0	0	1	0	2	2	0	0	0	0	0	0	4	1	11
WRONG SIZE	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Total	25	51	103	101	79	111	93	410	649	654	227	137	97	124	98	119	116	159	198	3551

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Table 2(c)
Number of Post-Implantation Complaints by Year of Complaint (Textured Devices)

Complaint	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total
ADVERSE REACTIONS	N/A	N/A	N/A	0	0	2	0	6	4	0	0	0	0	0	0	0	0	0	0	12
ANXIETY, STRESS, DEPRESSION	N/A	N/A	N/A	0	0	0	0	1	6	1	0	0	0	0	0	0	0	1	0	9
ASYMMETRY	N/A	N/A	N/A	0	0	0	6	3	6	7	6	1	1	3	0	0	4	0	0	37
AUTO-IMMUNE TYPE SYMPTOMS	N/A	N/A	N/A	0	0	0	2	30	36	41	10	5	7	7	0	0	0	0	0	138
BREAST PAIN	N/A	N/A	N/A	0	0	0	5	18	24	80	60	18	2	7	3	3	0	1	0	221
BUBBLES	N/A	N/A	N/A	6	22	54	29	16	25	11	14	1	2	0	1	4	1	2	5	193
CAPSULAR CONTRACTURE	N/A	N/A	N/A	0	0	0	2	81	81	193	125	45	21	65	34	33	34	26	13	753
COSMETIC/PARTICULATE MATTER	N/A	N/A	N/A	2	20	1	2	0	0	1	1	1	2	0	0	1	1	0	0	32
DEATH	N/A	N/A	N/A	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1
DEFECTIVE	N/A	N/A	N/A	2	29	0	0	3	0	0	1	0	0	0	0	0	0	0	0	35
DEFORMATION	N/A	N/A	N/A	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
DELAYED WOUND HEALING	N/A	N/A	N/A	0	0	0	1	0	2	2	4	0	1	2	0	0	0	0	0	12
DISLIKED RESULT	N/A	N/A	N/A	0	0	0	0	0	0	2	0	0	0	1	0	0	2	0	0	5
EXPOSURE/EXTRUSION/NECROSIS	N/A	N/A	N/A	0	1	3	3	0	7	5	8	1	0	0	0	1	2	3	1	35
FEVER	N/A	N/A	N/A	0	0	0	3	2	2	1	1	0	0	0	0	0	0	0	0	9
FLUID BUILD-UP	N/A	N/A	N/A	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2
GEL BLEED	N/A	N/A	N/A	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	2
HEMATOMA/SEROMA	N/A	N/A	N/A	0	2	8	1	52	20	48	28	1	1	4	1	0	2	0	2	170
HYPERTROPHIC SCARRING	N/A	N/A	N/A	0	0	0	0	0	6	10	8	0	0	2	0	0	0	0	0	26
DISPLACEMENT/MIGRATION	N/A	N/A	N/A	0	0	0	0	3	0	1	2	1	2	2	0	0	1	1	1	14
INFECTION	N/A	N/A	N/A	0	3	9	15	17	53	50	32	10	14	7	9	17	4	14	15	269
INFLAMMATION/IRRITATION/ SWELLING	N/A	N/A	N/A	0	0	1	1	0	2	6	13	0	0	3	1	0	0	0	0	27
INJURIES	N/A	N/A	N/A	0	0	0	0	2	51	0	0	0	0	0	0	0	0	0	0	53
JOINT PAIN	N/A	N/A	N/A	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	3
LOSS OF BREAST SENSATION	N/A	N/A	N/A	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1
LYMPHADENOPATHY	N/A	N/A	N/A	0	0	0	0	2	3	8	1	2	0	2	0	0	0	0	2	20
NO CODE AVAILABLE	N/A	N/A	N/A	0	2	3	5	18	16	14	8	0	1	1	1	0	4	4	0	77
PACKAGING/LABELING	N/A	N/A	N/A	0	1	2	5	1	3	0	2	2	4	0	1	1	2	1	2	27
PAIN	N/A	N/A	N/A	0	0	1	11	35	60	75	13	4	2	8	4	1	5	4	4	227
RUPTURE/LEAKAGE	N/A	N/A	N/A	27	12	12	24	62	65	97	78	79	129	150	147	189	207	209	231	1718
SILICONE (FEAR)	N/A	N/A	N/A	0	0	0	2	2	12	10	2	0	0	0	0	0	0	0	0	28
SILICONE GRANULOMA	N/A	N/A	N/A	0	0	0	0	0	0	0	0	0	0	1	0	0	2	0	0	3
STERILITY	N/A	N/A	N/A	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	0	4
TEAR/HOLE	N/A	N/A	N/A	0	9	70	55	5	23	6	1	2	5	2	2	1	2	0	1	184
WRINKLE	N/A	N/A	N/A	0	3	2	5	10	15	24	9	4	14	14	3	12	16	4	7	142
WRONG SIZE	N/A	N/A	N/A	0	2	4	2	2	0	2	2	0	0	0	0	0	0	0	0	16
More than 3 codes	N/A	N/A	N/A	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	3
Total	N/A	N/A	N/A	37	107	173	180	379	524	694	434	179	208	280	208	263	287	272	284	4509

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Table 3(a)
Number of Post-Implantation Complaints by Years *in vivo* (Smooth and Textured Devices)

Complaint	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	UNKN	Total
ADVERSE REACTIONS	4	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	14	21
ANXIETY, STRESS, DEPRESSION	1	3	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	13
ASYMMETRY	14	4	2	1	2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	54
AUTO-IMMUNE TYPE SYMPTOMS	21	17	12	18	16	11	12	4	2	3	2	0	0	1	0	0	0	0	0	335
BREAST PAIN	43	42	10	17	12	4	8	16	5	0	0	0	0	0	0	2	0	0	165	324
BUBBLES	36	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	181
CAPSULAR CONTRACTURE	189	134	80	83	80	57	46	35	18	17	7	5	2	1	0	0	0	0	0	538
COSMETIC/PARTICULATE MATTER	15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	42
DEATH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
DEFECTIVE	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	92
DEFORMATION	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
DELAYED WOUND HEALING	8	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	14
DISLIKED RESULT	4	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8
EXPOSURE/EXTRUSION/NECROSIS	25	4	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	44
FEVER	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	12
FLUID BUILD-UP	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
GEL BLEED	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
HEMATOMA/SEROMA	53	8	2	1	0	2	0	0	0	1	0	0	0	0	0	0	0	0	0	181
HYPERTROPHIC SCARRING	8	2	1	0	2	0	5	0	0	0	0	0	0	0	0	0	0	0	0	38
DISPLACEMENT/MIGRATION	7	0	0	1	0	0	3	0	1	1	0	0	1	0	0	0	0	0	0	17
INFECTION	209	18	6	4	3	2	0	2	2	0	0	0	0	0	0	0	0	0	0	324
INFLAMMATION/IRRITATION/ SWELLING	9	5	1	1	3	0	0	2	0	1	0	0	0	0	0	0	0	0	0	44
INJURIES	2	1	1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	132
JOINT PAIN	0	0	2	1	4	4	8	1	0	0	0	0	0	0	0	0	0	0	0	33
LOSS OF BREAST SENSATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
LYMPHADENOPATHY	0	1	0	0	1	0	1	2	1	0	0	0	0	0	0	0	0	0	0	28
NO CODE AVAILABLE	40	7	8	5	1	4	0	0	2	0	0	0	0	0	0	0	0	0	0	109
OPEN CAPSULOTOMY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
PACKAGING/LABELING	19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	44
PAIN	36	33	23	25	26	14	20	15	3	2	4	2	0	0	0	0	0	0	0	479
RUPTURE/LEAKAGE	512	181	162	167	168	186	204	186	185	112	106	84	72	46	19	12	4	6	1078	3490
SILICONE (FEAR)	3	2	4	13	5	4	2	0	0	1	0	0	0	0	0	0	0	0	0	43
SILICONE GRANULOMA	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
SLOSHING	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
STERILITY	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
TEAR/HOLE	36	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	315
WRINKLE	36	16	10	10	5	1	2	0	0	0	0	0	0	0	0	0	0	0	0	153
WRONG SIZE	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	17
More than 3 codes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
Total	1346	487	330	352	328	289	315	263	220	137	120	91	75	48	19	14	4	6	3616	8060

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Table 3(b)
Number of Post-Implantation Complaints by Years in vivo (Smooth Devices)

Complaint	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	UNKN	Total
ADVERSE REACTION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9	9
ANXIETY, STRESS, DEPRESSION	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9	10
ASYMMETRY	6	1	0	0	2	0	0	0	1	0	0	0	0	0	0	0	0	0	7	17
AUTO-IMMUNE TYPE SYMPTOMS	7	5	8	4	14	11	12	2	2	3	2	0	0	1	0	0	0	0	126	197
BREAST PAIN	5	6	1	1	4	1	8	15	5	0	0	0	0	0	0	2	0	0	55	103
BUBBLES	8	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	17	26
CAPSULAR CONTRACTURE	40	35	31	32	44	39	31	29	14	8	4	1	2	1	0	0	0	0	228	539
COSMETIC/PARTICULATE MATTER	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	17	25
DEFECTIVE	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	56	57
DELAYED WOUND HEALING	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	2
DISLIKED RESULT	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
EXPOSURE/EXTRUSION/NECROSIS	4	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	9
FEVER	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	3
HEMATOMA/SEROMA	4	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	5	11
HYPERTROPHIC SCARRING	0	0	1	0	2	0	5	0	0	0	0	0	0	0	0	0	0	0	4	12
DISPLACEMENT/MIGRATION	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	1	3
INFECTION	26	3	0	1	0	2	0	2	2	0	0	0	0	0	0	0	0	0	19	55
INFLAMMATION/IRRITATION/SWELLING	1	2	0	0	2	0	0	2	0	1	0	0	0	0	0	0	0	0	9	17
INJURIES	2	1	1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	73	79
JOINT PAIN	0	0	2	0	3	4	8	1	0	0	0	0	0	0	0	0	0	0	12	30
LOSS OF BREAST SENSATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
LYMPHADENOPATHY	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	6	8
NO CODE AVAILABLE	24	1	4	0	0	4	0	0	2	0	0	0	0	0	0	0	0	0	64	99
OPEN CAPSULOTOMY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
PACKAGING/LABELING	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	13	17
PAIN	9	8	1	12	9	7	20	14	3	2	3	2	0	0	0	0	0	0	162	252
RUPTURE/LEAKAGE	236	81	42	60	66	90	108	111	114	61	60	35	50	28	19	12	4	6	589	1772
SILICONE (FEAR)	0	1	2	10	5	4	2	0	0	1	0	0	0	0	0	0	0	0	24	49
SLOSHING	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2
TEAR/HOLE	16	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	114	131
WRINKLE	2	6	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	11
WRONG SIZE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
TOTAL	407	151	96	121	151	163	200	178	143	76	70	38	52	30	19	14	4	6	1632	3551

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Table 3(c)
Number of Post-Implantation Complaints by Years in vivo (Textured Devices)

Complaint	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	UNKN	Total
ADVERSE REACTIONS	4	2	1	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	5	12	
ANXIETY, STRESS, DEPRESSION	1	2	1	1	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	4	9	
ASYMMETRY	8	3	2	1	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	23	37	
AUTO-IMMUNE TYPE SYMPTOMS	14	12	4	14	2	0	0	2	0	0	0	0	0	0	N/A	N/A	N/A	90	138	
BREAST PAIN	38	36	9	16	8	3	0	1	0	0	0	0	0	0	N/A	N/A	N/A	110	221	
BUBBLES	28	1	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	164	193	
CAPSULAR CONTRACTURE	149	99	49	51	36	18	15	6	4	9	3	4	0	0	0	N/A	N/A	310	753	
COSMETIC/PARTICULATE MATTER	7	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	25	32	
DEATH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	1	1	
DEFECTIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	35	35	
DEFORMATION	1	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	1	
DELAYED WOUND HEALING	7	1	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	4	12	
DISLIKED RESULT	1	0	1	2	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	1	5	
EXPOSURE/EXTRUSION/NECROSIS	21	4	2	1	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	7	35	
FEVER	6	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	3	9	
FLUID BUILD-UP	2	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	2	
GEL BLEED	1	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	1	2	
HEMATOMA/SEROMA	49	8	2	1	0	1	0	0	0	0	0	0	0	0	N/A	N/A	N/A	109	170	
HYPERTROPHIC SCARRING	8	2	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	16	26	
DISPLACEMENT/MIGRATION	7	0	0	1	0	0	1	0	1	1	0	0	1	0	N/A	N/A	N/A	2	14	
INFECTION	183	15	6	3	3	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	59	269	
INFLAMMATION/IRRITATION/ SWELLING	8	3	1	1	1	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	13	27	
INJURIES	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	53	53	
JOINT PAIN	0	0	0	1	1	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	1	3	
LOSS OF BREAST SENSATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	1	1	
LYMPHADENOPATHY	0	1	0	0	1	0	1	0	1	0	0	0	0	0	N/A	N/A	N/A	16	20	
NO CODE AVAILABLE	16	6	4	5	1	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	45	77	
PACKAGING/LABELING	15	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	12	27	
PAIN	27	25	22	13	17	7	0	1	0	0	1	0	0	0	N/A	N/A	N/A	114	227	
RUPTURE/LEAKAGE	276	100	120	107	102	96	96	75	71	51	46	49	22	18	0	N/A	N/A	489	1718	
SILICONE (FEAR)	3	1	2	3	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	19	28	
SILICONE GRANULOMA	0	3	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	3	
STERILITY	2	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	2	4	
TEAR/HOLE	20	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	164	184	
WRINKLE	34	10	8	10	5	1	2	0	0	0	0	0	0	0	N/A	N/A	N/A	72	142	
WRONG SIZE	3	2	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	11	16	
More than 3 codes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	3	3	
Total	939	336	234	231	177	126	115	85	77	61	50	53	23	18	0	N/A	N/A	1984	4509	

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Table 4(a)

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Table 4(b)

Percent Post Implantation Complaints by Years in vivo (Smooth Devices)

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Table 4(c)
Percent Post Implantation Complaints by Years in vivo (Textured Devices)

Complaint	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	UNKN	Total
ADVERSE REACTIONS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0.01	
ANXIETY, STRESS, DEPRESSION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
ASYMMETRY	0.01	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.01	0.02	
AUTO-IMMUNE TYPE SYMPTOMS	0.01	0.01	0	0.01	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.05	0.07	
BREAST PAIN	0.04	0.02	0	0.01	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.06	0.11	
BUBBLES	0.03	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.08	0.1	
CAPSULAR CONTRACTURE	0.15	0.05	0.03	0.03	0.02	0.01	0.01	0	0	0	0	0	0	0	N/A	N/A	N/A	0.16	0.39	
COSMETIC/PARTICULATE MATTER	0.01	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.01	0.02	
DEATH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
DEFECTIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.02	0.02	
DEFORMATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
DELAYED WOUND HEALING	0.01	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0.01	
DISLIKED RESULT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
EXPOSURE/EXTRUSION/NECROSIS	0.02	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0.02	
FEVER	0.01	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
FLUID BUILD-UP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
GEL BLEED	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
HEMATOMA/SEROMA	0.05	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
HYPERTROPHIC SCARRING	0.01	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.06	0.09	
DISPLACEMENT/MIGRATION	0.01	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.01	0.01	
INFECTION	0.19	0.01	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.03	0.14	
INFLAMMATION/IRRITATION/ SWELLING	0.01	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.01	0.01	
INJURIES	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.03	0.03	
JOINT PAIN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
LOSS OF BREAST SENSATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
LYMPHADENOPATHY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.01	0.01	
NO CODE AVAILABLE	0.02	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.02	0.04	
PACKAGING/LABELING	0.02	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.01	0.01	
PAIN	0.03	0.01	0.01	0.01	0.01	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.06	0.12	
RUPTURE/LEAKAGE	0.29	0.05	0.06	0.06	0.05	0.05	0.05	0.04	0.04	0.03	0.02	0.03	0.01	0.01	0	N/A	N/A	N/A	0.25	0.89
SILICONE (FEAR)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.01	0.01	
SILICONE GRANULOMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
STERILITY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	
TEAR/HOLE	0.02	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.08	0.1	
WRINKLE	0.04	0.01	0	0.01	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.04	0.07	
WRONG SIZE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0.01	0.01	
More than 3 codes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	N/A	N/A	N/A	0	0	

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Table 5(a)

		Pre-Implantation Complaints By Year (Smooth and Textured Devices)																			
Complaint		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total
BUBBLES		1	1	2	7	22	58	32	17	29	13	14	1	2	0	1	9	1	2	7	219
COSMETIC/PARTICULATE MATTER		0	0	2	5	27	5	3	0	0	1	1	1	2	0	0	1	3	3	3	57
PACKAGING/LABELING		0	1	2	3	2	5	6	1	5	0	2	2	4	0	1	3	3	2	2	44
STERILITY		0	0	0	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	0	4
SHIPPING DAMAGE		0	0	0	1	1	0	0	1	0	0	0	0	0	0	0	1	0	0	0	4
WRONG SIZE		0	0	0	0	2	5	2	2	2	0	2	2	0	0	0	0	0	0	0	17
Total		1	2	6	16	54	73	43	23	36	16	19	6	8	0	2	14	7	7	12	345

		Pre-Implantation Complaints By Year (Smooth Devices)																			
Complaint		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total
BUBBLES		1	1	2	1	0	4	3	1	4	2	0	0	0	0	0	5	0	0	2	26
COSMETIC/PARTICULATE MATTER		0	0	2	3	7	4	1	0	0	0	0	0	0	0	0	0	2	3	3	25
PACKAGING/LABELING		0	1	2	3	1	3	1	0	2	0	0	0	0	0	0	2	1	1	0	17
SHIPPING DAMAGE		0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	3
WRONG SIZE		0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Total		1	2	6	8	9	12	5	1	6	2	0	0	0	0	0	8	3	4	5	72

		Pre-Implantation Complaints By Year (Textured Devices)																			
Complaint		1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	Total
BUBBLES		N/A	N/A	N/A	6	22	54	29	16	25	11	14	1	2	0	1	4	1	2	5	193
COSMETIC/PARTICULATE MATTER		N/A	N/A	N/A	2	20	1	2	0	0	1	1	1	2	0	0	1	1	0	0	32
PACKAGING/LABELING		N/A	N/A	N/A	0	1	2	5	1	3	0	2	2	4	0	1	1	2	1	2	27
STERILITY		N/A	N/A	N/A	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	0	4
SHIPPING DAMAGE		N/A	N/A	N/A	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
WRONG SIZE		N/A	N/A	N/A	0	2	4	2	2	0	2	2	0	0	0	0	0	0	0	0	16
Total		N/A	N/A	N/A	8	45	61	38	22	30	14	19	6	8	0	2	6	4	3	7	273

Mentor Low Bleed Gel-Filled Mammary Prostheses Complaint Analysis

Complaint	Smooth Gel Devices		Textured Gel Devices		Overall	
	Number	Rate	Number	Rate	Number	Rate
Bubbles	26	0.021%	193	0.100%	219	0.070%
Cosmetic	25	0.021%	32	0.017%	57	0.018%
Labeling	6	0.005%	10	0.005%	16	0.005%
Packaging	11	0.009%	17	0.009%	28	0.009%
Shipping Damage	3	0.002%	1	0.001%	4	0.001%
Sterility	0	0.000%	4	0.002%	4	0.001%
Wrong Size	1	0.001%	16	0.008%	17	0.005%
TOTAL	72	0.059%	273	0.141%	345	0.110%
Number of Devices		121464		193458		314922